CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
22511Orig1s000

OTHER REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date: April 20, 2010

To: Donna Griebel, M.D., Director
Division of Gastroenterology Products (DGP)

Through: Claudia Karwoski, PharmD, Director
Division of Risk Management (DRISK)
Sharon Mills, RN, BSN, CCRP
Senior Patient Labeling Reviewer, Acting Team Leader
Division of Risk Management (DRISK)

From: Jessica Diaz, RN, BSN
Patient Labeling Reviewer
Division of Risk Management (DRISK)

Subject: DRISK Review of Patient Labeling (Medication Guide

Drug Name(s): VIMOVO (naproxen and esomeprazole magnesium) Delayed Release Tablets

Application Type/Number: NDA 22-511

Applicant/sponsor: Pozen, Inc.

OSE RCM #: 2009-1607

1 INTRODUCTION

This memorandum is in response to a request by the Division of Gastroentergology Products (DGP) for the Division of Risk Management (DRISK) to review the Medication Guide for VIMOVO (naproxen and esomeprazole magnesium) Delayed Release Tablets.

On June 30, 2009, Pozen, Inc in collaboration with Astra Zeneca submitted New Drug Application (NDA) 22-511 for VIMOVO (naproxen and esomeprazole magnesium) Delayed Release Tablets. The proposed indication for VIMOVO (naproxen and esomeprazole magnesium) Delayed Release Tablets is for relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk for developing NSAID-associated gastric ulcers.

Please let us know if DGP would like a meeting to discuss theis review or any of our changes prior to sending to the Applicant.

2 MATERIAL REVIEWED

- Draft VIMOVO (naproxen and esomeprazole magnesium) Tablets Prescribing Information (PI) submitted June 30, 2009, and revised by the review division throughout the review cycle.
- Draft VIMOVO (naproxen and esomeprazole magnesium) Delayed Release Tablets PI with Medication Guide submitted November 11, 2009 and revised by the review division throughout the review cycle and provided to DRISK on April 13, 2010

3 RESULTS OF REVIEW

In our review of the Medication Guide, we have:

- simplified wording and clarified concepts where possible
- ensured that the MG is consistent with the PI
- removed unnecessary or redundant information
- ensured that the MG meets the Regulations as specified in 21 CFR 208.24
- ensured that the MG meets the criteria as specified in FDA's Guidance Useful Written Consumer Medication Information (published July 2006)
- ensured that the Vimovo MG is consistent with the currently approved NSAID MG template
- added information after the required NSAID language about the esomeprazole magnesium component of the product, and general information about Vimovo

Our annotated MG is appended to this memo. Any additional revisions to the PI should be reflected in the MG.

Please let us know if you have any questions.

21 Pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22511	ORIG-1	POZEN INC	PN 400 NAPROXEN/ESOMEPRAZOLE MAGNESIUM

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JESSICA M DIAZ
04/20/2010

CLAUDIA B KARWOSKI
04/20/2010
concur

RPM FILING REVIEW

(Including Memo of Filing Meeting)

To be completed for all new NDAs, BLAs, and Efficacy Supplements (except SE8 and SE9)

Application Information		
NDA # 22-511 BLA#	NDA Supplement #:S- BLA STN #	Efficacy Supplement Type SE-
Proprietary Name: Vimovo Established/Proper Name: naproxen and esomeprazole magnesium Dosage Form: Tablets Strengths: 375mg/20mg and 500mg/20mg		
Applicant: Pozen Agent for Applicant (if applicable):		
Date of Application: 30 JUN 2009 Date of Receipt: 30 JUN 2009 Date clock started after UN:		
PDUFA Goal Date: 30 APR 2010	Action Goal Date (if different):	
Filing Date: 29 AUG 2009	Date of Filing Meeting: 19 AUG 2009	
Chemical Classification: (1,2,3 etc.) (original NDAs only) Type 4		
Proposed indication(s)/Proposed change(s): Signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in patients at risk of developing NSAID associated gastric ulcers		

Type of Original NDA: AND (if applicable)	☐ 505(b)(1) ☒ 505(b)(2)
Type of NDA Supplement: ***If 505(b)(2): Draft the "505(b)(2) Assessment" form found at:*** ***http://inside.fda.gov:9003/CDER/OfficeofNewDrugs/ImmediateOffice/ucm027499.html*** ***and refer to Appendix A for further information.***	☐ 505(b)(1) ☐ 505(b)(2)
Review Classification: ***If the application includes a complete response to pediatric WR, review classification is Priority.*** ***If a tropical disease priority review voucher was submitted, review classification is Priority.***	☒ Standard ☐ Priority ☐ Tropical Disease Priority Review Voucher submitted
Resubmission after withdrawal? ☐	Resubmission after refuse to file? ☐
Part 3 Combination Product? ☐ ***If yes, contact the Office of Combination Products (OCP) and copy them on all Inter-Center consults***	☐ Drug/Biologic ☐ Drug/Device ☐ Biologic/Device
☐ Fast Track ☐ Rolling Review ☐ Orphan Designation ☐ Rx-to-OTC switch, Full ☐ Rx-to-OTC switch, Partial ☐ Direct-to-OTC Other:	☐ PMC response ☐ PMR response: ☐ FDAAA [505(o)] ☐ PREA deferred pediatric studies [21 CFR 314.55(b)/21 CFR 601.27(b)] ☐ Accelerated approval confirmatory studies (21 CFR 314.510/21 CFR 601.41) ☐ Animal rule postmarketing studies to verify clinical

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